

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
9 October 2003 (09.10.2003)

PCT

(10) International Publication Number  
**WO 03/082402 A2**

(51) International Patent Classification<sup>7</sup>: **A61N**  
(21) International Application Number: PCT/US03/09211  
(22) International Filing Date: 26 March 2003 (26.03.2003)  
(25) Filing Language: English  
(26) Publication Language: English  
(30) Priority Data:  
10/112,301 28 March 2002 (28.03.2002) US  
(71) Applicant (for all designated States except US): **NORTH-STAR NEUROSCIENCE, INC.** [US/US]; 2401 - 4th Avenue, Suite 500, Seattle, WA 98121 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(72) Inventor; and  
(75) Inventor/Applicant (for US only): **GLINER, Bradford, Evan** [US/US]; 4368 230th Way SE, Sammamish, WA 98075 (US).  
(74) Agent: **PARKER, Paul, T.**; Perkins Coie LLP, P.O. Box 1247, Seattle, WA 98111-1247 (US).

**Published:**

— with declaration under Article 17(2)(a); without abstract; title not checked by the International Searching Authority

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



**WO 03/082402 A2**

(54) Title: ELECTRODE GEOMETRIES FOR EFFICIENT NEURAL STIMULATION

(57) Abstract:

**BEST AVAILABLE COPY**

## ELECTRODE GEOMETRIES FOR EFFICIENT NEURAL STIMULATION

## CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application relates to and incorporates by reference U.S. Patent Application Serial No. 09/978,134, entitled "Systems and Methods for Automatically Optimizing Stimulus Parameters and Electrode Configurations for Neuro-Stimulators," filed on October 15, 2001.

## TECHNICAL FIELD

[0002] The present invention relates generally to electrodes suitable for neural stimulation. More particularly, the present invention includes a variety of electrode geometries or designs directed toward enhancing the efficiency of neural stimulation, and/or increasing electrode reliability.

## BACKGROUND

[0003] A variety of medical procedures involve electrically monitoring and/or stimulating neural tissue, such as regions of the cortex or spinal cord. For example, epileptogenic foci localization may be accomplished through cortical monitoring procedures; and various neurologically based pain conditions may be treated with cortical or spinal stimulation. Electrical signals may be exchanged with neural tissue through an electrode that includes a set of electrically conductive contacts.

[0004] The effectiveness of a neural stimulation procedure may be related to the electric field distribution produced by or associated with an electrode employed in the procedure. In general, the electric or stimulation field distribution depends upon a) electrode design; b) the particular electrode contacts to which electrical stimulation signals are applied; and c) the magnitudes and polarities of applied stimulation signals. An electrode's design encompasses the structure and spatial organization of its contacts, and/or the as-manufactured electrical couplings thereto. In order to maximize the likelihood that neural stimulation will be effective, an electrode design

should be capable of producing an intended or desired type of stimulation field distribution. Depending upon stimulation requirements, an electrode design capable of providing flexibility with respect to manners in which stimulation field distributions may be established, configured, or tailored may be advantageous.

[0005] Neural microelectrodes are designed for micro-scale neural monitoring and/or stimulation, that is, highly localized signal exchange with very small neural populations or single neurons. Neural microelectrode types may include patch clamp or pipette microelectrodes; etched and/or micromachined needle electrodes or probes; and annular microelectrodes. An annular microelectrode capable of preferentially stimulating a single neuron soma is described in U.S. Patent No. 5,411,540. Unlike the procedures disclosed in U.S. Patent No. 5,411,540, many neural monitoring and/or stimulation procedures involve signal exchange with sizeable neural populations, i.e., hundreds, thousands, many thousands, or even millions of neurons. The microelectrodes disclosed in U.S. Patent No. 5,411,540 accordingly have very limited applicability to such procedures.

[0006] Neural microelectrode arrays include multiple neural microelectrodes organized in a regular pattern and formed or mounted upon a substrate. Although a neural microelectrode array may be capable of monitoring and/or stimulating a larger neural population than an individual neural microelectrode, such an array may be undesirably complex and/or expensive from a manufacturing standpoint.

[0007] Grid electrodes may facilitate macro-scale neural monitoring and/or stimulation, that is, neural tissue monitoring and/or stimulation involving hundreds, thousands, hundreds of thousands, or perhaps millions of neurons. FIG. 1 is a plan view of a conventional grid electrode 100, which comprises a plurality of contacts 110 uniformly arranged in an array or a set of generally rectangular or rectilinear patterns; a lead wire 120 coupled to each contact 110; one or more electrode leads 130 into which lead wires 120 may be organized and/or routed; and a medium, substrate, or backing 140 upon and/or within which the contacts 110, the lead wires 120, and possibly portions of the electrode leads 140 reside. Conventional grid electrodes 100

are available from Ad-Tech Medical Instrument Corporation of Racine, WI. In general, the contacts 110, the lead wires 120, one or more portions of the electrode leads 130, and the substrate 140 are formed from biocompatible materials in a manner readily understood by those skilled in the art.

[0008] Conventional grid electrodes 100 may include a significant number of contacts 110. Such grid electrodes 100 maintain a one-to-one ratio between the number of contacts 110 and the number of lead wires 120. Thus, a conventional eight-by-eight grid electrode 100 having sixty-four contacts 110 includes sixty-four lead wires 120. Any given lead wire 120 may be coupled to a desired stimulation signal via an external signal routing interface that is connected to a stimulation signal source in a manner readily understood by those skilled in the art. Conventional grid electrodes 100 may facilitate a limited degree of simulation field configurability through selective coupling between specific contacts 110 and particular stimulation signals.

[0009] An electrode implant procedure may be highly invasive from a surgical standpoint, possibly requiring, for example, a craniotomy. Electrode reliability is therefore of paramount importance. Unfortunately, the large number of lead wires 120 resulting from a grid electrode's one-to-one contact to lead wire ratio increases the complexity and decreases the reliability of an electrode lead 130. Thus, conventional grid electrode arrays may not be suitable for use in procedures that require implanted electrodes.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is a plan view of a conventional grid electrode.

[0011] FIG. 2A is a plan view of an annular electrode configured for macro-scale neural stimulation according to an embodiment of the invention.

[0012] FIG. 2B is a plan view of an annular electrode positioned upon a neural tissue surface region and configured to provide macro-scale stimulation to a neural tissue within and/or beneath the neural tissue surface region according to an embodiment of the invention.

[0013] FIG. 3A is a plan view of an arc electrode according to an embodiment of the invention.

[0014] FIG. 3B is a plan view of an arc electrode according to another embodiment of the invention.

[0015] FIG. 4A is a plan view of an electrode exhibiting nonuniform contact separation according to an embodiment of the invention.

[0016] FIG. 4B is a plan view of an electrode exhibiting nonuniform contact separation according to another embodiment of the invention.

[0017] FIG. 4C is a plan view of a circular multi-contact electrode exhibiting nonuniform contact separation according to an embodiment of the invention.

[0018] FIG. 5A is a plan view of an electrode exhibiting nonuniform contact sizes, areas, or peripheries according to an embodiment of the invention.

[0019] FIG. 5B is a plan view of a circular multi-contact electrode exhibiting nonuniform contact sizes or areas according to an embodiment of the invention.

[0020] FIG. 5C is a plan view of a circular multi-contact electrode exhibiting nonuniform contact sizes or areas and nonuniform contact separation according to an embodiment of the invention.

[0021] FIG. 6A is a plan view of an electrode having selectively interconnected contacts according to an embodiment of the invention.

[0022] FIG. 6B is a plan view of an electrode having selectively interconnected contacts according to another embodiment of the invention.

[0023] FIG. 6C is a plan view of an electrode having selectively interconnected contacts and nonuniform contact distribution according to an embodiment of the invention.

[0024] FIG. 6D is a plan view of an electrode having selectively interconnected contacts and nonuniform contact distribution according to another embodiment of the invention.

[0025] FIG. 6E is a plan view of an electrode having selectively interconnected contacts and nonuniform contact areas or peripheries according to an embodiment of the invention.

[0026] FIG. 6F is a plan view of an electrode having selectively interconnected contacts and nonuniform contact areas according to another embodiment of the invention.

[0027] FIG. 6G is a plan view of a circular multi-contact electrode having selectively interconnected contacts and nonuniform contact areas according to an embodiment of the invention.

[0028] FIG. 6H is a plan view of a circular multi-contact electrode having selectively interconnected contacts and nonuniform contact areas according to another embodiment of the invention.

[0029] FIG. 6I is a plan view of a circular multi-contact electrode having selectively interconnected contacts, nonuniform contact areas, and nonuniform contact group distribution according to an embodiment of the invention.

#### DETAILED DESCRIPTION

[0030] The following discussion is presented to enable a person skilled in the art to make and use the invention. The general principles described herein may be applied to embodiments and applications other than those detailed below without departing from the spirit and scope of the present invention as defined by the appended claims. The present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

[0031] The present invention comprises a variety of electrode designs or geometries that may provide enhanced neural stimulation efficiency. Enhanced neural stimulation efficiency may be particularly valuable or important when stimulation is directed toward inducing and/or enhancing neuroplasticity for neural function rehabilitation and/or other purposes. The present invention additionally comprises electrode designs that may decrease electrode complexity and thus increase electrode reliability. Increased electrode reliability may be particularly important in neural stimulation situations because electrodes may be implanted on a permanent or long term basis, possibly through a significantly invasive surgical implant procedure. The use of electrodes for intracranial neural stimulation is described in U.S. Patent Application Serial No. 09/978,134, entitled "Systems and Methods for

Automatically Optimizing Stimulus Parameters and Electrode Configurations for Neuro-Stimulators," filed on October 15, 2001.

[0032] Depending upon neural stimulation requirements and/or electrode embodiment details, electrodes constructed in accordance with the present invention may selectively employ concentric contacts; arc and/or generally arc shaped contacts; variations in contact number, positioning, spacing, and/or distribution; variations in contact shape, area, and/or periphery; and/or conductive on-electrode links or interconnections between particular contacts to provide an intended type of stimulation field distribution, as described in detail hereafter.

[0033] FIG. 2A is a plan view of an annular electrode 200 configured for macro-scale neural stimulation according to an embodiment of the present invention. The annular electrode 200 comprises a central contact 210 and one or more annular contacts 212a, 212b that encircle the central contact 210. The electrode 200 also includes a lead wire 220 corresponding to each contact 210, 212a, 212b; one or more electrode leads 230 into which lead wires 220 may be grouped, organized, and/or routed; and a medium, substrate, or backing 240. The central contact 210, the annular contacts 212a, 212b, the lead wires 220, and possibly portions of the electrode leads 230 are carried by the substrate 240. The contacts 210, 212a, 212b, the lead wires 220, one or more portions of the electrode leads 230, and the substrate 240 are formed from biocompatible materials known to persons skilled in the art. Suitable materials for the contacts 210, 212a, 212b include stainless steel, platinum, platinum-iridium, iridium oxide, or gold. It will be appreciated that the contacts 210, 212a, 212b can comprise other materials and/or coatings.

[0034] The substrate 240 of the annular electrode may be soft and/or flexible, such that it may readily conform to a wide variety of neural tissue surfaces. Each contact 210, 212a, 212b is sufficiently large that the annular electrode 200 may deliver stimulation to a macro-scale neural tissue region, which may include a large number of neural cell bodies. In one embodiment, a surface area enclosed by an outermost annular contact 212b is many times larger than the surface area associated with a single neural cell body, even when

considering large types of neurons such as pyramidal neurons. The annular electrode 200 may be suitable for delivering stimulation to a region of the cerebral cortex; for example, the electrode 200 may be implanted proximate to a cortical region associated with controlling a particular type of mental or physical function.

[0035] FIG. 2B is a plan view of an annular electrode 200 positioned upon a neural tissue surface region 290 and configured to provide macro-scale stimulation to neural tissue within and/or beneath the neural tissue surface region 290 according to an embodiment of the invention. The annular electrode 200 may be positioned with respect to a given neural tissue surface region 290 through a surgical implant procedure, such as described in U.S. Patent Application Serial No. 09/978,134. The annular electrode 200 may be implanted, for example, subdurally to deliver electrical stimulation to a particular portion of the cerebral cortex. An electrode lead 230 may be positioned such that it minimally contacts and/or impacts neural tissue, and may be routed away from neural tissue via an opening in the skull through which the annular electrode 200 was implanted. A stimulation field distribution produced by an annular electrode 200 may be characterized by a high degree of radial uniformity, which may be desirable in certain neural stimulation applications.

[0036] FIG. 3 is a plan view of an arc electrode 300 according to an embodiment of the invention. In one embodiment, the arc electrode 300 comprises a central contact 310, which may be disk-shaped, and a set of arc contacts 312 concentrically and/or peripherally positioned or arranged relative to the central contact 310. The electrode 300 further comprises lead wires 320 coupled to the central and arc contacts 310, 312; an electrode lead 330 into which lead wires 320 may be grouped, organized, and/or routed; and a medium, substrate, or backing 340. As with the electrode 200, the contacts 310, 312, portions of the lead wires 320, and possibly portions of the electrode lead 330 are carried by the substrate 340.

[0037] The central and each arc contact 310, 312 may comprise a compositionally stable, biologically compatible, electrically conductive material such as Stainless Steel, Platinum, Platinum-Iridium, Iridium Oxide, Gold,



and/or other materials and/or coatings. The arc electrode 300 may be manufactured using conventional electrode manufacturing processes or techniques.

[0038] An arc contact 312 may exhibit a curved, bent, or arc-like shape, and may be characterized by a radius of curvature and an arc length. Depending upon the requirements of the stimulation field, the number, curvature, length, and/or position of the arcs may vary. In alternate embodiments, one or more arc contacts 312 may exhibit v-like or other types of curved or angled shapes.

[0039] Arc contacts 312 may be grouped or organized into particular patterns, which may be generally circular, elliptical, or otherwise shaped. Any given arc contact pattern may be positioned or oriented in a predetermined manner with respect to the central contact 310 and/or other contact patterns. In the embodiment shown in FIG. 3A, the arc contacts 312 are grouped into a first circular pattern 314 that generally surrounds the central contact 310; and a second circular pattern 316 that generally surrounds the first circular pattern 314. In the embodiment shown in FIG. 3B, the arc contacts 312 are grouped into an elliptical pattern. Those skilled in the art will understand that additional, fewer, and/or other types of arc contact patterns are possible in other embodiments.

[0040] The central contact 310 and each arc contact 312 may be coupled to corresponding lead wires 320. Any given lead wire 320 may be coupled to a particular stimulation signal at a stimulation signal source. Thus, within the first and/or second circular patterns 314, 316, successively positioned arc contacts 312 may be coupled to stimulation signals having identical or different magnitudes, biases, and/or temporal characteristics. In an analogous manner, arc contacts 312 that exhibit a given positional correspondence from one circular pattern 314, 316 to another may be coupled to stimulation signals having identical or different magnitudes, biases, and/or temporal characteristics. Hence, an arc electrode 300 constructed in accordance with the present invention may be configured to provide a wide variety of stimulation field distributions.

[0041] The present invention encompasses arc electrode embodiments beyond those described above. For example, an arc electrode 300 may omit

the central contact 310, include additional or fewer arc contacts 312, and/or include one or more conventional annular contacts 112. As another example, an arc electrode 300 may include a centrally positioned contact grid in place of the central contact 310, in which case individual contacts within the contact grid may be coupled to one or more particular stimulation signals provided by a stimulation signal source. As yet another example, an arc electrode 300 may comprise one or more arc contacts 312 positioned in one or more non-concentric manners. Any given embodiment may be selected in accordance with stimulation field distribution requirements associated with a given neural stimulation situation.

[0042] In addition to arc electrode embodiments 300 such as those described above, the present invention also encompasses a variety of grid-like and/or other types of multi-contact electrode embodiments. In accordance with the present invention, one manner of affecting an electrical or stimulation field distribution is through nonuniform contact distribution, separation, or pitch. The description hereafter details various multi-contact electrode embodiments that may selectively exploit nonuniform contact separation to provide or approximate a desired or intended type of stimulation field distribution. Relative to various electrode embodiments described hereafter, like and/or analogous elements may be indicated with like reference numbers to aid understanding.

[0043] FIG. 4A is a plan view of an electrode 400 having nonuniform or uneven contact distribution, separation, or spacing according to an embodiment of the invention. In one embodiment, such an electrode 400 comprises a plurality of disk-shaped contacts 410a, 410b, 410c; a lead wire 420 coupled to each contact 410; a set of electrode leads 430 into which lead wires 420 may be organized and/or routed; and a medium, substrate, or backing 440 that carries the contacts 410a, 410b, 410c, the lead wires 420, and portions of the electrode leads 430. The contacts 410a-c can have other shapes in addition to or in lieu of disk shapes. The lead wires 420, one or more portions of the electrode leads 430, and the substrate 440 may be formed from biocompatible materials known in the art. Additionally, the contacts 410a-c may comprise a biologically compatible, electrically

conductive material in a manner identical or analogous to that described above.

[0044] Relative to any given electrode embodiment, one or more contact organizational patterns may be defined. Depending upon embodiment details, the spacing between the contacts 410a-c within a subset of contacts may be nonuniform, and/or the spacing or separation between sets of contacts may be nonuniform. As such, the spacing between contacts in a pattern may be nonuniform, and/or the spacing between patterns of contacts may be nonuniform. In FIG. 4A, the contacts 410a are organized in accordance with a first pattern or distribution (shown unshaded); the contacts 410b are organized in accordance with a second pattern or distribution (shown cross-hatched); and the contacts 410c are organized in accordance with a third pattern (shown in solid). The center-to-center or equivalent spacing between the contacts 410a organized in accordance with the first pattern is less than that of the contacts 410b, 410c organized in accordance with the second and third patterns. In addition, the distance between a border or edge corresponding to the first pattern and an equivalent type of border or edge corresponding to the second pattern differs from the distance between a border or edge corresponding to the second pattern and an equivalent type of border or edge corresponding to the third pattern. Thus, the distribution or spatial density of the contacts 410a-c may vary across the surface of an electrode 400 constructed in accordance with the present invention.

[0045] Other types of contact organizations or patterns may be defined with respect to any given embodiment and/or alternate embodiments. Moreover, any given contact organizational pattern may appear multiple times in the context of a single embodiment. The spatial distribution or density of contacts 410a-c within a contact organizational pattern may be nonuniform, and/or the spatial separation between particular contact organizational patterns may vary across an electrode's surface. Furthermore, a contact distribution pattern may be defined and/or employed based upon particular types of stimulation signals that may be applied to some or all contacts 410a-c within the pattern.

[0046] FIG. 4B is a plan view of an electrode 450 having nonuniform contact separation according to another embodiment of the invention. The electrode 450 shown in FIG. 4B may comprise identical and/or analogous types of elements as those shown in FIG. 4A, such that the number and/or positioning of such elements may differ in accordance with a contact organization scheme. In FIG. 4B, the contacts 410a are organized in accordance with a first pattern or distribution (shown unshaded), and the contacts 410b are organized in accordance with a second pattern (shown in solid). To simplify understanding, individual lead wires and an electrode lead are not shown in FIG. 4B. Notwithstanding, each contact 410a, 410b may be coupled to a corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner identical or generally analogous to that shown in FIG. 4A. Each element of the electrode 450 may be implemented using biocompatible materials.

[0047] As shown in FIG. 4B, the spatial density of the contacts 410a, 410b varies across the surface of the electrode 450. In particular, the center-to-center or equivalent spacing between any two contacts 410a organized in accordance with the first pattern differs from the center-to-center spacing between a contact 410a organized in accordance with the first pattern and a contact 410b organized in accordance with the second pattern.

[0048] FIG. 4C is a plan view of a circular multi-contact electrode 460 having nonuniform contact separation according to an embodiment of the invention. In the embodiment shown, the circular multi-contact electrode 460 comprises a plurality of the contacts 410a-c that reside upon and/or within a generally circular substrate, medium, or backing 442. As in FIG. 4B, individual lead wires and an electrode lead are not indicated in FIG. 4C to simplify understanding. Notwithstanding, each contact 410a-c may be coupled to a corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner identical, essentially identical, or analogous to that shown in FIG. 4A; and each element of the circular multi-contact electrode 460 may be implemented using conventional biocompatible materials, in a manner previously described. In FIG. 4C, a contact 410a organized in accordance with a first pattern is shown unshaded. Contacts

410b organized in accordance with a second pattern are shown cross-hatched, and contacts 410c organized in accordance with a third pattern are shown in black. In accordance with the present invention, the spatial distribution of the contacts 410a-c in FIG. 4C is nonuniform across the electrode 460.

[0049] In various embodiments, the separation distance between or spatial distribution of the particular contacts 410a-c and/or contact organizational patterns may be a function of distance from a set of the reference contacts 410a-c and/or reference contact organizational patterns. Thus, in one embodiment, the contacts 410a-c organized within any given organizational pattern may exhibit a uniform contact to contact separation distance, whereas separation distances between radially successive contact organizational patterns may increase or decrease with distance from a centrally-positioned contact organizational pattern.

[0050] With respect to electrodes 400, 450, 460 exhibiting nonuniform contact distribution, the particular contacts 410a-c may be coupled to particular stimulation signals at a stimulation signal source. In contrast to neural stimulation delivered through a conventional grid electrode 100 such as that shown in FIG. 1, stimulation delivered using an electrode exhibiting nonuniform contact separation or distribution may produce nonuniform stimulation field densities within or across predetermined stimulation regions. This may advantageously enhance neural stimulation efficacy by concentrating or reducing stimulation in particular target areas.

[0051] In accordance with the present invention, one manner of providing an electrode having desired or intended neural stimulation characteristics involves the use of contacts of different peripheries or areas. The description hereafter details various multi-contact electrode embodiments having nonuniform contact periphery or area, possibly in conjunction with nonuniform contact separation. Relative to various embodiments described hereafter, like and/or analogous elements may be indicated with like reference numbers for ease of understanding.

[0052] FIG. 5A is a plan view of an electrode 500 exhibiting variations in contact sizes, areas, and/or peripheries according to an embodiment of the

invention. Such an electrode 500 may comprise at least one disk shaped contact 510 characterized by a first size, area, or circumference; one or more identically or essentially identically shaped contacts 512 characterized by a second size, area, or circumference; a lead wire 520 coupled to each contact 510, 512; a set of electrode leads 530 into which lead wires 520 may be organized and/or routed; and a medium, substrate, or backing upon and/or within which the contacts 510, 512, portions of the lead wires 520, and possibly portions of the electrode lead 530 may reside. The contacts 510, 512, lead wires 520, substrate 540, and one or more portions of the electrode leads 530 may be implemented using biocompatible materials in a manner identical and/or analogous to that described above.

[0053] A contact 510 characterized by the first size or area may be larger than a contact 512 characterized by the second size or area. In the embodiment shown in FIG. 5A, a larger-area disk shaped contact 510 is centrally positioned relative to a plurality of smaller-area disk shaped contacts 512 that are organized in accordance with a particular pattern. Depending upon embodiment details and/or neural stimulation requirements, electrodes constructed in accordance with the present invention may include various numbers of contacts characterized by the first size or area, the second size or area, other sizes or areas, and/or other contact shapes. Such contacts may be positioned, organized, or oriented with respect to each other and/or a substrate 540 in a wide variety of manners. Additional embodiments that employ a larger-area central contact 510 and a plurality of peripheral smaller-area contacts 512 are described in detail hereafter.

[0054] FIG. 5B is a plan view of a circular multi-contact electrode 550 exhibiting nonuniform contact sizes according to an embodiment of the invention. In one embodiment, the circular multi-contact electrode 550 comprises a larger-area central contact 510; a plurality of smaller-area peripheral contacts 512 positioned relative to the central contact 510 in accordance with a predetermined pattern; and a substrate, medium, or backing 542 upon and/or within which the contacts 510, 512 may reside. To simplify understanding, individual lead wires and an electrode lead are not shown in FIG. 5B. Notwithstanding, each contact 510, 512 may be coupled

to a corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner analogous to that shown in FIG. 5A. Each element of the circular multi-contact electrode 550 may be implemented using conventional biocompatible materials, in a manner previously indicated.

[0055] FIG. 5C is a plan view of a circular multi-contact electrode 560 exhibiting nonuniform contact sizes and nonuniform contact separation according to an embodiment of the invention. The circular multi-contact electrode 560 of FIG. 5C may be structurally similar or analogous to the circular multi-contact electrode 460 of FIG. 4C, and may comprise a larger-area central contact 510 and a set of peripheral contacts 512 that reside upon and/or within a generally circular substrate or medium 542. The smaller-area peripheral contacts 512 may be organized or positioned in accordance with a set of predetermined patterns relative to the larger-area central contact 510. As in FIGs. 4C and 5B, individual lead wires and an electrode lead are not shown in FIG. 5C for ease of understanding. Nonetheless, each contact 510, 512 may be coupled to a corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner analogous to that shown in FIG. 5A. In addition, each element of the circular multi-contact electrode 560 may be implemented in a previously indicated manner using conventional biocompatible materials.

[0056] Relative to a smaller-area contact 512, a larger-area contact 510 exhibits a larger signal transfer area. A larger-area contact 510 may therefore facilitate more efficient delivery of larger magnitude stimulation signals than a smaller-area contact 512. An electrode characterized by nonuniform contact area may advantageously exhibit a lower effective impedance than, for example, a conventional grid electrode 100, and may provide enhanced efficiency neural stimulation.

[0057] Another manner of providing or approximating an intended electric or stimulation field distribution is through the selective use of electrode-based or on-electrode couplings, links, connections, and/or shunts between contacts. In the context of the present invention, an electrode-based or on-electrode contact coupling may comprise a contact-to-contact coupling and/or

connection that originates at one contact and terminates at one or more other contacts. On-electrode contact couplings may include one or more portions that reside within, upon, above and/or beneath a substrate, and/or proximate to the substrate's spatial bounds. The description hereafter details various multi-contact electrode embodiments that may selectively exploit on-electrode contact couplings or interconnections, possibly in conjunction with nonuniform contact separation and/or nonuniform contact area. Relative to various embodiments described hereafter, like and/or analogous elements may be indicated with like reference numbers for ease of understanding.

[0058] FIG. 6A is a plan view of an electrode 600 having selectively coupled, connected, and/or interconnected contacts according to an embodiment of the invention. In one embodiment, the electrode 600 comprises a plurality of contacts 610; one or more electrically interdependent, isoelectric, and/or essentially isoelectric contact groups 616; lead wires 620 corresponding to each contact 610 and each isoelectric contact group 616; a set of electrode leads 630 into which lead wires 620 may be grouped or organized; and a substrate or medium 640 upon and/or within which the contacts 610, the contact groups 616, portions of the lead wires 620, and possibly portions of the electrode leads 630 may reside. In one embodiment, the lead wires 620, the electrode lead 630, and the substrate 640 are formed from conventional biocompatible materials.

[0059] In one embodiment, an isoelectric contact group 616 comprises two or more contacts 610 having on-electrode couplings, links, connections, interconnections and/or shunts 618 therebetween. A contact interconnection 618 within an isoelectric contact group 616 may reside in a particular plane relative to contact, contact group, and/or electrode surfaces intended to impinge or impress upon a patient's neural tissue. Contacts 610 and/or contact groups 616 may be implemented using one or more biologically compatible, electrically conductive materials, such as Stainless Steel, Platinum, Platinum-Iridium, and/or other materials. Contact groups 616 and/or contact interconnections 618 may be formed using highly conductive materials, materials having variable and/or adjustable conductive properties, and/or materials exhibiting particular impedance characteristics.



[0060] An electrode 600 having contact couplings and/or interconnections 618 in accordance with the present invention may be manufactured in a variety of manners. For example, various types of preformed isoelectric contact groups 616 may be cut, stamped, formed, molded, or otherwise manufactured in a manner analogous to that for contacts 610. One or more portions of a preformed contact group 616 may exhibit bar, barbell, rectangular, or other types of shapes. Preformed contact groups 616 may be positioned upon or within a substrate 640 and coupled or connected to lead wires 620 in a manner essentially identical to that for contacts 610. As another manufacturing example, contacts 610, lead wires 620, and/or an electrode lead 630 may be formed, placed, and/or organized using conventional techniques, after which desired contact interconnections 618 may be formed or fabricated using selective masking and material deposition techniques, thereby forming isoelectric contact groups 616. As yet another example, contacts 610 organized in accordance with a given pattern and exhibiting selective contact interconnections 618 may be formed using flex circuit and/or membrane circuit fabrication techniques. One or more portions of a flex or membrane circuit may be encased, encapsulated, covered, or surrounded by Silicone, Silastic® (Dow Corning Corporation, Midland, MI), and/or other materials to ensure appropriate biocompatibility.

[0061] FIG. 6B is a plan view of an electrode 650 having selective contact interconnections 618 according to another embodiment of the invention. The electrode 650 shown in FIG. 6B may be structurally identical or analogous to that shown in FIG. 6A, with the exception that it comprises a plurality of contact groups 616, and omits individual contacts 610 that are electrically independent. The contact interconnections 618 of FIG. 6B reside in different positions relative to those in FIG. 6A.

[0062] FIG. 6C is a plan view of an electrode 652 having selectively coupled and/or interconnected contacts and nonuniform contact separation or spacing according to an embodiment of the invention. The electrode 652 shown in FIG. 6C exhibits a structural and/or geometric correspondence to the electrode 400 shown in FIG. 4A. In one embodiment, the electrode 652 comprises a plurality of isoelectric contact groups 616 that reside upon a

substrate or medium 640. For ease of understanding, lead wires and an electrode lead are not shown in FIG. 6C. Notwithstanding, any given contact group 616 may be coupled to a corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner identical or essentially identical to that previously described. Each element of the electrode 652 of FIG. 6C may be implemented using biocompatible materials in manners previously described.

[0063] FIG. 6D is a plan view of an electrode 654 having selectively coupled and/or interconnected contacts and nonuniform contact separation according to another embodiment of the invention. The electrode 654 shown in FIG. 6D exhibits a structural correspondence to the electrode 450 shown in FIG. 4B. In one embodiment, the electrode 654 comprises a plurality of isoelectric contact groups 616 that reside upon a substrate or medium 640. Lead wires and an electrode lead are not shown in FIG. 6D to simplify understanding. Nonetheless, any given contact group 616 may be coupled to a corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner identical or essentially identical to that previously described. Each element of the electrode 654 of FIG. 6D may be implemented using biocompatible materials in manners previously described.

[0064] FIG. 6E is a plan view of an electrode 660 having selectively interconnected contacts and nonuniform contact areas according to an embodiment of the invention. The electrode 660 shown in FIG. 6E exhibits a structural correspondence to the electrode 500 shown in FIG. 5A. In one embodiment, the electrode 660 comprises a substrate 640 upon and/or within which a larger-area central contact 610, a plurality of smaller-area peripheral contacts 612, and a plurality of isoelectric contact groups 616 may reside in accordance with a set of predetermined patterns. To simplify understanding, lead wires and an electrode lead are not shown in FIG. 6E. Nonetheless, the central contact 610, any given peripheral contact 612, and any given contact group 616 may each be coupled to a corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner identical or essentially identical to that previously described. Each element of the

electrode 660 of FIG. 6E may be implemented using biocompatible materials in manners previously described.

[0065] FIG. 6F is a plan view of an electrode 662 having selectively interconnected contacts and nonuniform contact areas according to another embodiment of the invention. The electrode 662 shown in FIG. 6F exhibits a structural correspondence to the electrode 500 of FIG. 5A and the electrode 660 of FIG. 6E. The electrode 662 of FIG. 6F may comprise a substrate or medium 640 upon and/or within which a central contact 610 and a peripherally positioned isoelectric contact group 616 reside. In the embodiment shown, the isoelectric contact group 616 surrounds the central contact 610. Thus, the electrode 662 of FIG. 6F may provide a generally uniform stimulation field distribution capable of approximating that of an annular electrode 200. In FIG. 6F, lead wires and an electrode lead are not shown to simplify understanding. Nonetheless, the central contact 610 and the contact group 616 may each be coupled to a corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner identical or essentially identical to that described above. Each element of the electrode 662 of FIG. 6F may be implemented using biocompatible materials in manners previously described.

[0066] FIG. 6G is a plan view of a circular multi-contact electrode 670 having selectively interconnected contacts and nonuniform contact areas according to an embodiment of the invention. The electrode 670 of FIG. 6G exhibits a structural correspondence to the electrode 550 of FIG. 5B. The electrode 670 of FIG. 6G may comprise a larger-area central contact 610; a plurality of contact groups 616 peripherally positioned with respect thereto; and a generally circular substrate or medium 642 upon and/or within which the central contact 610 and the contact groups 616 may reside. Due to the positioning of the contact groups 616 relative to the central contact 610, the electrode 670 of FIG. 6G may provide a reasonably or generally uniform stimulation field distribution capable of approximating that of an annular electrode 200. To simplify understanding, lead wires and an electrode lead are not shown in FIG. 6G. Notwithstanding, the central contact 610 and any given contact group 616 may be coupled to corresponding lead wires, and

lead wires may be organized and/or grouped into an electrode lead in a manner identical or essentially identical to that previously described. Each element of the electrode 670 of FIG. 6G may be implemented using biocompatible materials in manners previously described.

[0067] FIG. 6H is a plan view of a circular multi-contact electrode 672 having selectively interconnected contacts and nonuniform electrode area according to another embodiment of the invention. The electrode 672 of FIG. 6H exhibits a structural correspondence to the electrode 550 of FIG. 5B and the electrode 670 of FIG. 6G. The electrode 670 of FIG. 6H comprises a larger-area central contact 610 and a surrounding contact group 616, which may be mounted or positioned upon and/or within a generally circular substrate or backing 642. The electrode 672 of FIG. 6H may provide a generally or highly uniform stimulation field distribution capable of approximating that of an annular electrode 200 due to the geometric structure of its contact group 616 and the position or orientation of the contact group 616 relative to the central contact 610. To simplify understanding, lead wires and an electrode lead are not shown in FIG. 6H. Notwithstanding, the central contact 610 and the given contact group 616 may each be coupled to a corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner identical or essentially identical to that previously described. Each element of the electrode 672 of FIG. 6H may be implemented using biocompatible materials in manners previously described.

[0068] FIG. 6I is a plan view of a circular multi-contact electrode 680 having selectively interconnected contacts, nonuniform contact areas, and nonuniform contact group separation according to an embodiment of the invention. The electrode 680 of FIG. 6I maintains a structural and/or geometric correspondence to the electrode 560 of FIG. 5C, and comprises a larger area central contact 610 and a plurality of contact groups 616 peripherally positioned relative thereto, where the central contact 610 and the contact groups 616 may be positioned or mounted upon and/or within a generally circular substrate or medium 642. To simplify understanding, lead wires and an electrode lead are not shown in FIG. 6H. Notwithstanding, the central contact 610 and any given contact group 616 may be coupled to a

corresponding lead wire, and lead wires may be organized and/or grouped into an electrode lead in a manner identical or essentially identical to that previously described. Each element of the electrode 680 of FIG. 6I may be implemented using biocompatible materials in manners previously described.

[0069] An electrode having selectively positioned on-electrode contact groups 616, which may be formed from appropriate types of couplings or interconnections 618 between contacts 610, may produce a predetermined or preconfigured stimulation field distribution capable of providing an intended or desired type of neural stimulation. In addition, such an electrode may advantageously exhibit reduced complexity, and thus enhanced reliability, since any given isoelectric contact group 616 may be coupled to a single lead wire rather than coupling individual lead wires to each contact 610 within the contact group 616.

[0070] Electrodes may be designed in accordance with the present invention based upon stimulation signal characteristics and/or stimulation field distribution requirements associated with a given neural stimulation situation. Electrode embodiments described herein may be modified and/or generalized in a variety of manners. For example, an annular or arc electrode may include one or more on-electrode contact interconnections. As another example, one or more electrode embodiments described above may include fewer or additional contacts and/or contact groups. As yet another example, an electrode designed in accordance with the present invention may include one or more arc shaped, disk shaped, and/or otherwise shaped contacts, which may vary in spatial distribution and/or contact area or periphery. Such an electrode may further include on-electrode contact interconnections or couplings between identically, similarly, and/or differently shaped contacts. The present invention encompasses these and other variations, and is limited only by the following claims.

## CLAIMS

I/We claim:

- [c1] 1. An annular electrode configured for macro-scale neural stimulation comprising:  
a substrate configured to be implanted in a human body;  
an inner contact carried by the substrate; and  
a first outer contact carried by the substrate, the first outer contact being annular and surrounding the inner contact,  
wherein an area enclosed by the first outer contact is many times greater than a neural cell body area.
- [c2] 2. The electrode of claim 1, further comprising a second outer contact that surrounds the first outer contact.
- [c3] 3. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body; and  
an electrical contact carried by the substrate, the electrical contact being an arcuate segment.
- [c4] 4. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body; and  
a plurality of electrical contacts carried by the substrate, wherein at least one of the electrical contacts comprises an arcuate segment contact.
- [c5] 5. The electrode of claim 4, wherein the plurality of electrical contacts comprises a plurality of arcuate segment contacts positioned relative to the substrate in accordance with an elliptical type of pattern.

- [c6] 6. The electrode of claim 4, wherein the plurality of electrical contacts comprises a plurality of arcuate segment contacts positioned relative to the substrate in accordance with a set of concentric elliptical pattern types.
- [c7] 7. The electrode of claim 4, wherein the plurality of electrical contacts includes a set of disk shaped contacts.
- [c8] 8. The electrode of claim 7 wherein:  
the plurality of electrical contacts includes a plurality of arcuate segment contacts, and  
the set of disk shaped contacts are centrally positioned relative to at least two arcuate segment contacts.
- [c9] 9. The electrode of claim 7, wherein the set of disk shaped contacts is centrally positioned relative to each arcuate segment contact.
- [c10] 10. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body;  
a disk shaped electrical contact carried by the substrate; and  
a plurality of first arcuate segment electrical contacts carried by the substrate, the first arcuate segment electrical contacts being positioned in an elliptical pattern around the disk shaped electrical contact.
- [c11] 11. The electrode of claim 10, further comprising a plurality of second arcuate segment electrical contacts carried by the substrate and peripherally positioned in an elliptical pattern relative to the plurality of first arcuate segment electrical contacts.
- [c12] 12. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body; and  
a plurality of electrical contacts carried by the substrate, wherein the electrical contacts are arranged on the substrate in a pattern in

which the electrical contacts are spatially distributed in a nonuniform manner.

- [c13] 13. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body;  
a first plurality of electrical contacts carried by the substrate and spaced apart by a first distance; and  
a second plurality of electrical contacts carried by the substrate and spaced apart by a second distance different than the first distance.
- [c14] 14. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body;  
a first set of electrical contacts carried by the substrate and organized in accordance with a first pattern; and  
a second set of electrical contacts carried by the substrate and organized in accordance with a second pattern,  
wherein a separation distance between a contact within the first set of electrical contacts and a contact within the second set of electrical contacts is unequal to a separation distance between contacts within one from the group of the first set of electrical contacts and the second set of electrical contacts.
- [c15] 15. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body;  
a first set of electrical contacts carried by the substrate; and  
a second set of electrical contacts carried by the substrate,  
wherein at least one contact within the first set of electrical contacts has an essentially identical shape as and a larger periphery than at least one contact within the second set of electrical contacts.



- [c16] 16. The electrode of claim 15, wherein at least one contact within the second set of electrical contacts is disk shaped.
- [c17] 17. The electrode of claim 15, wherein each contact within the second set of electrical contacts is disk shaped.
- [c18] 18. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body;  
a centrally positioned electrical contact carried by the substrate and having a first area; and  
a plurality of peripherally positioned electrical contacts carried by the substrate, at least one peripherally positioned electrical contact having an essentially identical shape as the centrally positioned contact and a second area different than the first area.
- [c19] 19. The electrode of claim 18, wherein each peripherally positioned electrical contact has an essentially identical shape as the centrally positioned contact.
- [c20] 20. The electrode of claim 19, wherein each peripherally positioned electrical contact has a smaller area than the centrally positioned contact.
- [c21] 21. The electrode of claim 18, wherein each peripherally positioned electrical contact has an essentially identical shape and a smaller area than the centrally positioned contact.
- [c22] 22. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body;  
a first electrical contact carried by the substrate;  
a second electrical contact carried by the substrate; and  
an on-electrode contact coupling between the first and second electrical contacts.

[c23] 23. The electrode of claim 22, wherein the first electrical contact, the second electrical contact, and the on-electrode contact coupling therebetween comprise an isoelectric contact group.

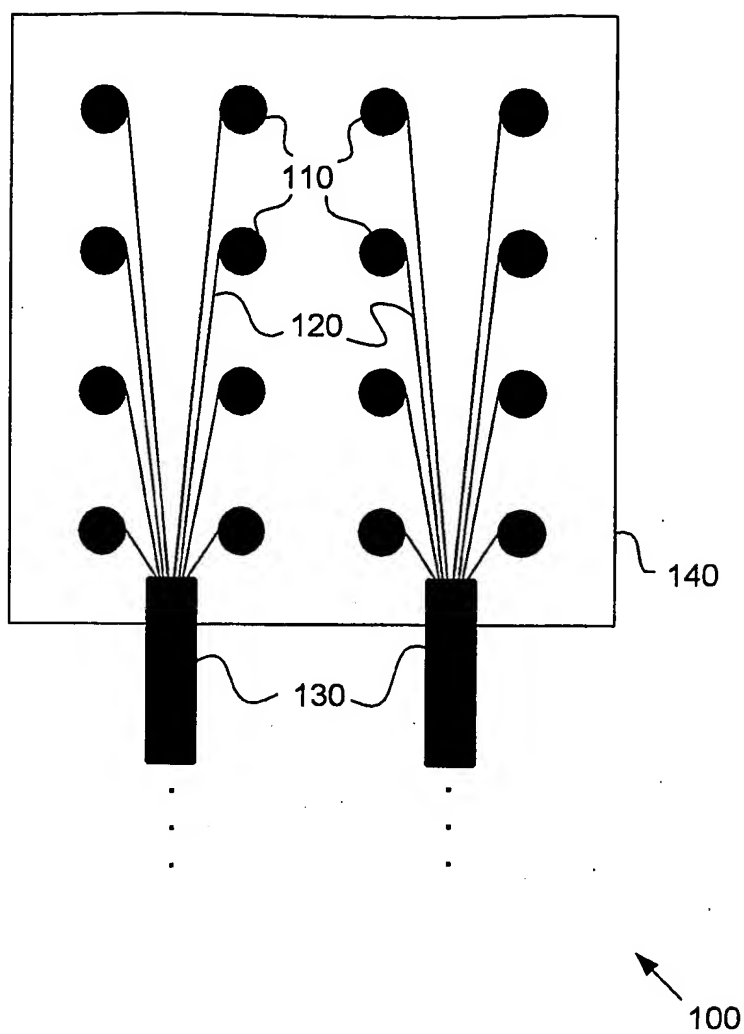
[c24] 24. The electrode of claim 22, further comprising a third electrical contact carried by the substrate that is electrically independent from the first electrical contact.

[c25] 25. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body; and  
a plurality of electrical contacts carried by the substrate and spatially distributed in a nonuniform manner, the plurality of electrical contacts including at least two contacts having different peripheries.

[c26] 26. The electrode of claim 25, wherein the plurality of electrical contacts includes at least two contacts having an on-electrode coupling therebetween.

[c27] 27. An electrode suitable for neural stimulation comprising:  
a substrate configured to be implanted in a human body; and  
a plurality of electrical contacts carried by the substrate and spatially distributed in a nonuniform manner; and  
an on-electrode coupling between at least two contacts within the plurality of electrical contacts.

[c28] 28. The electrode of claim 27, wherein at least two contacts within the plurality of electrical contacts have different peripheries.



**FIG. 1**  
**(PRIOR ART)**

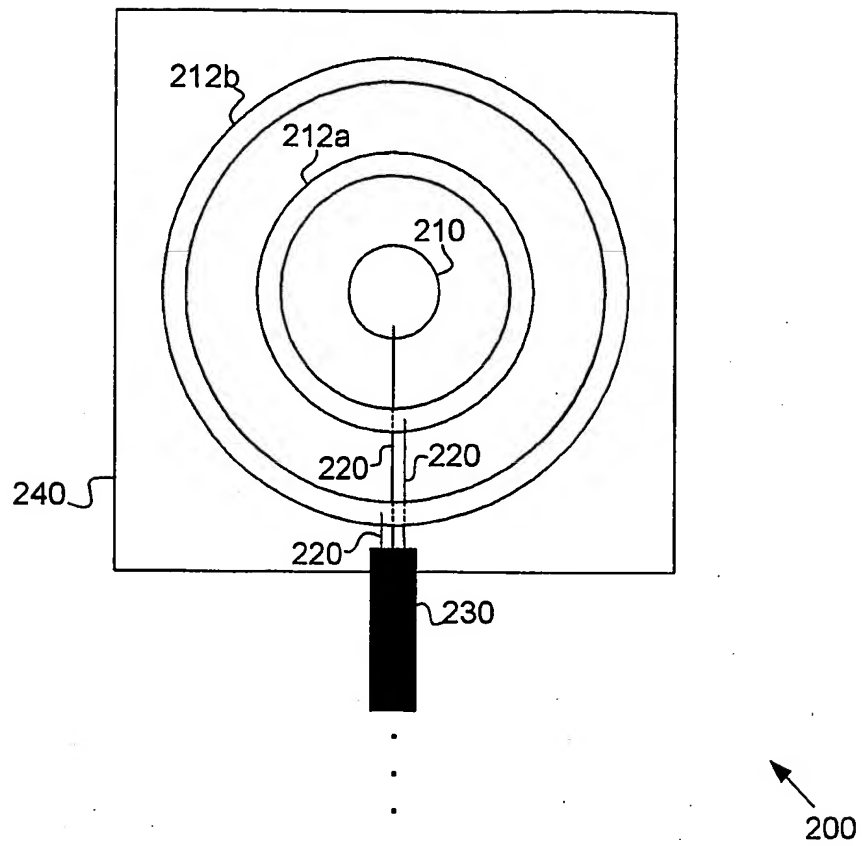
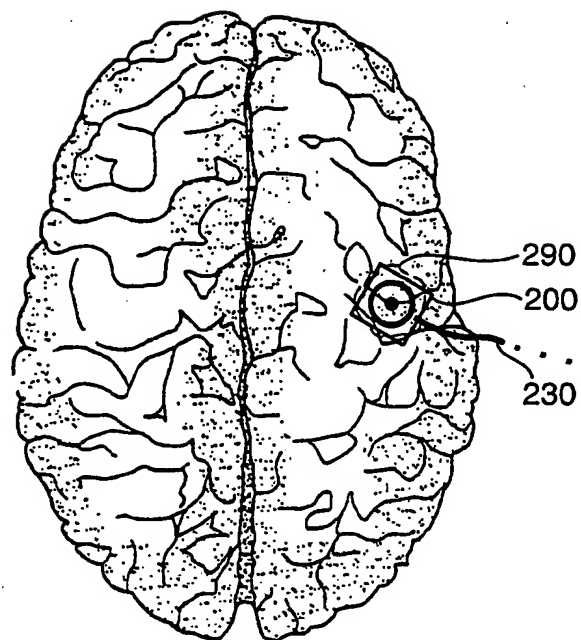


FIG. 2A



**FIG. 2B**

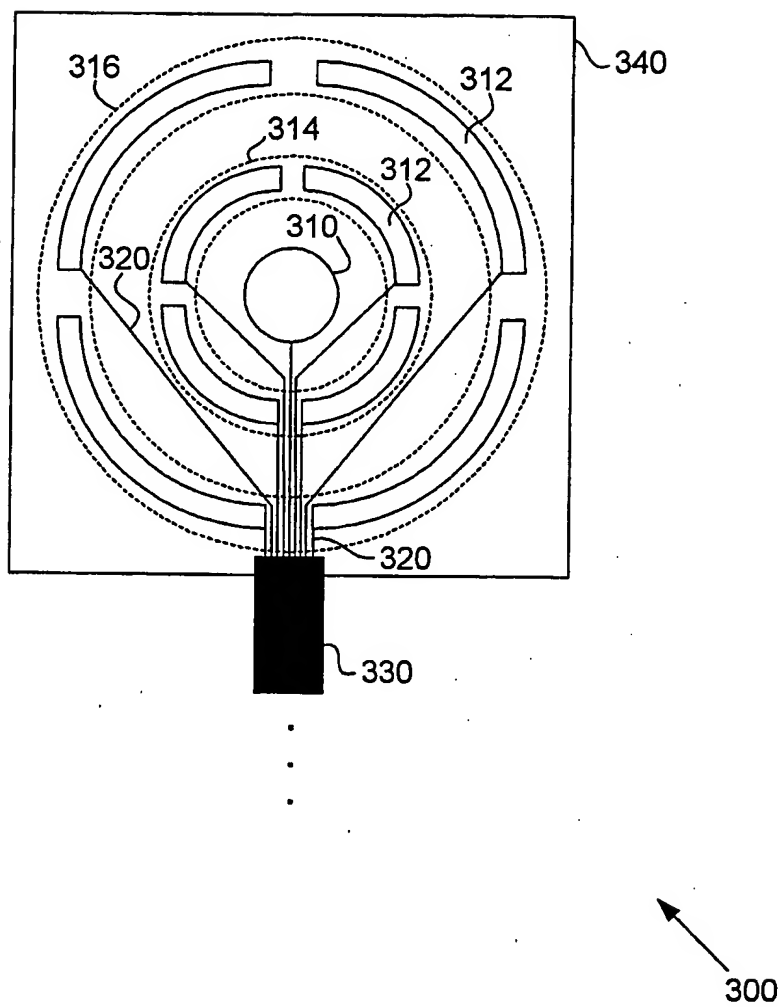
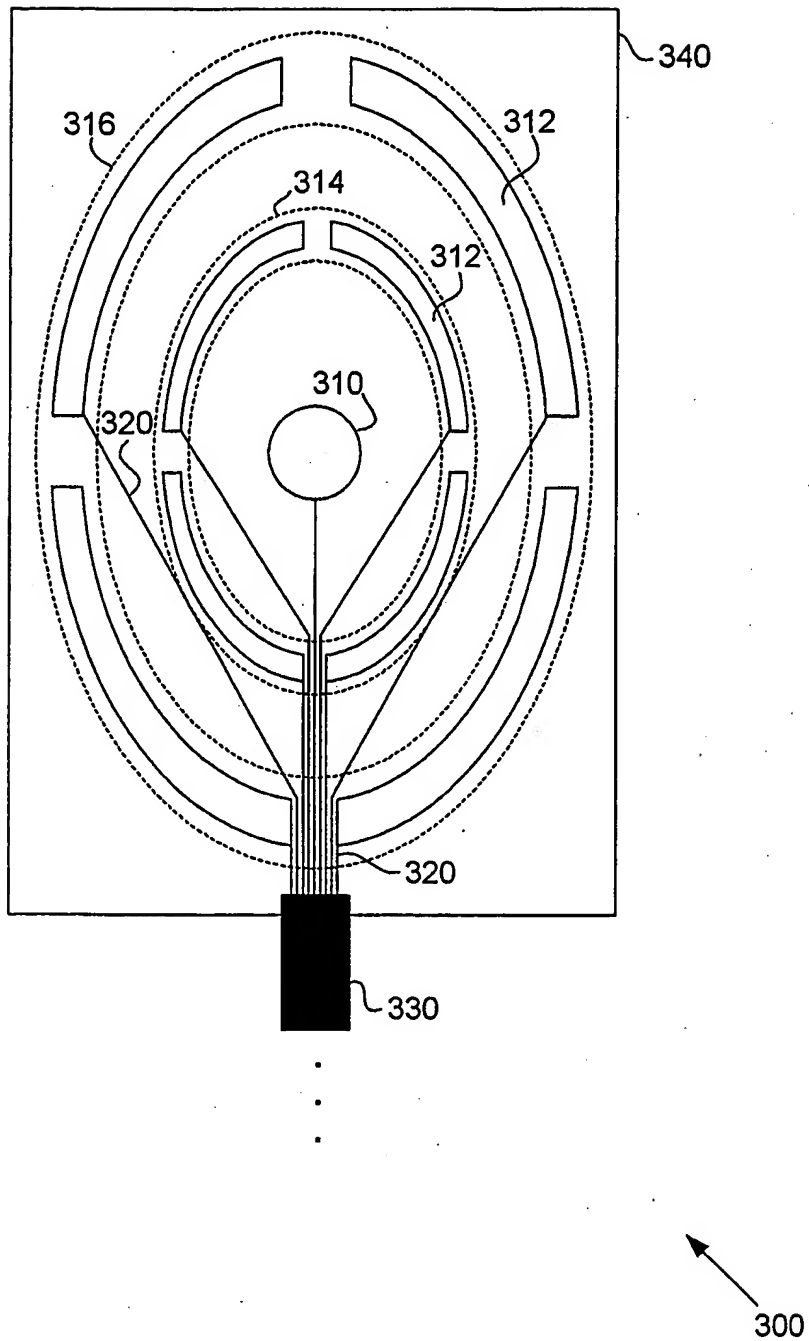


FIG. 3A

**FIG. 3B**

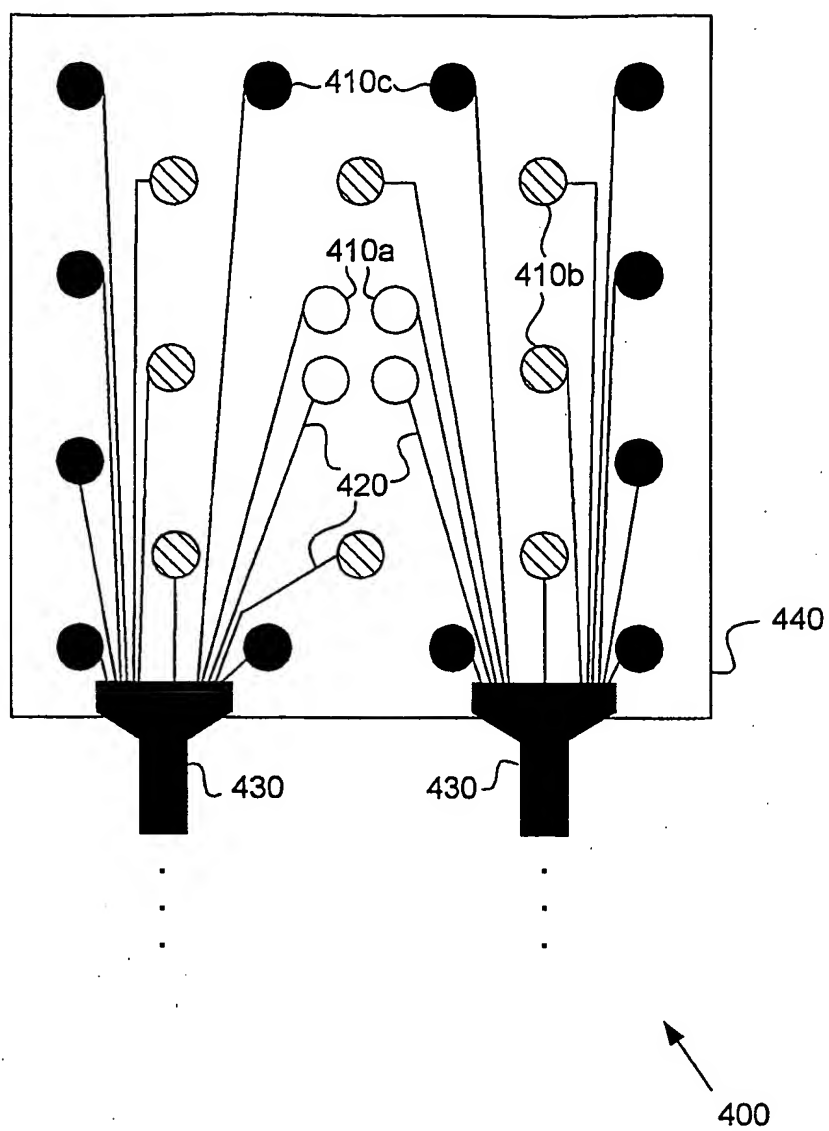


FIG. 4A



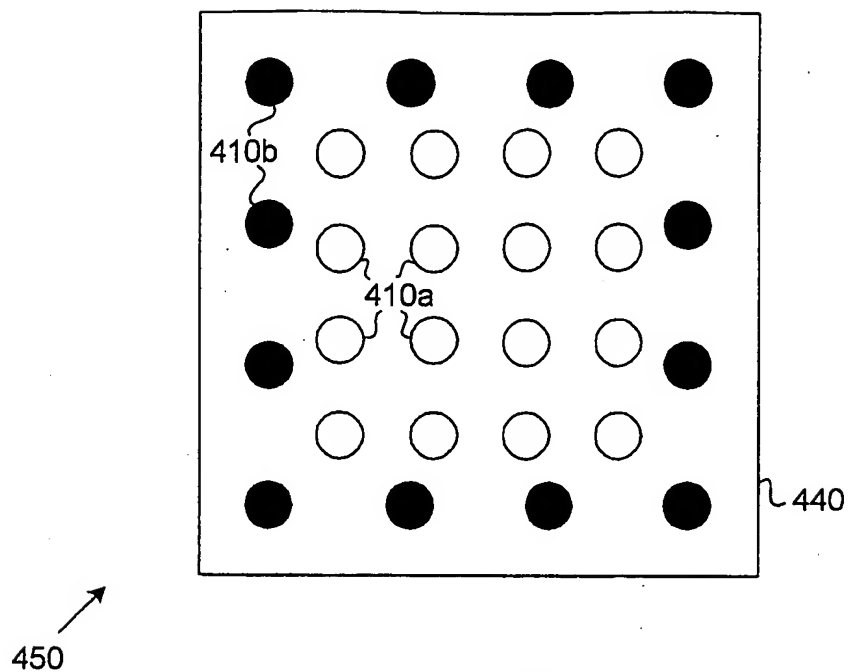


FIG. 4B

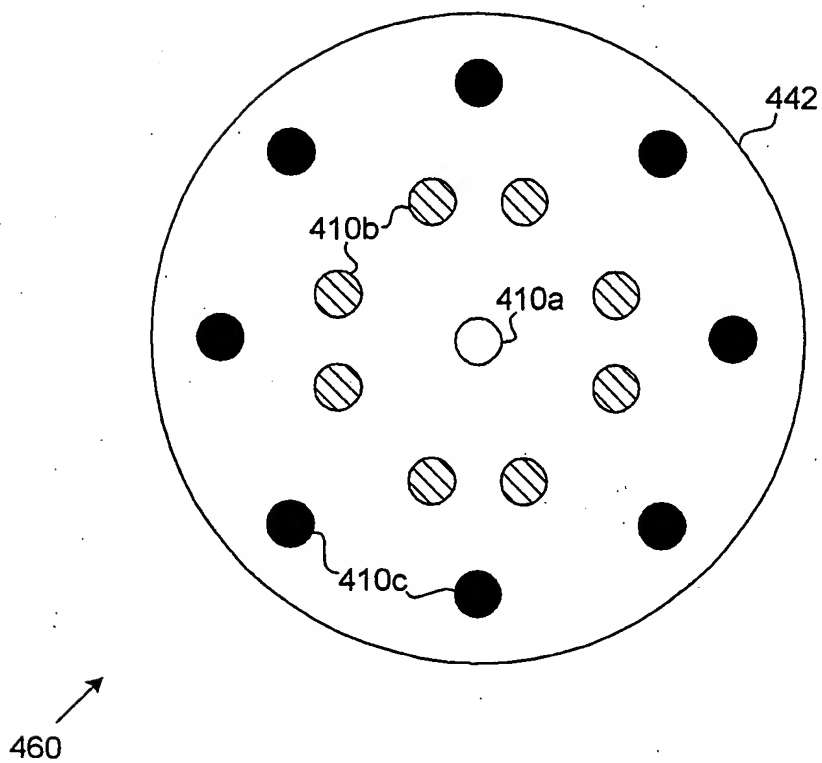


FIG. 4C

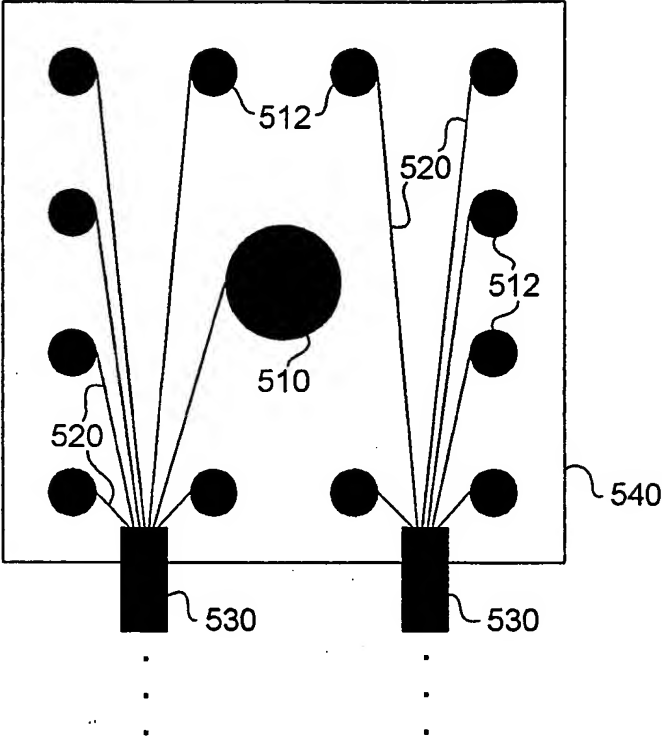


FIG. 5A

500

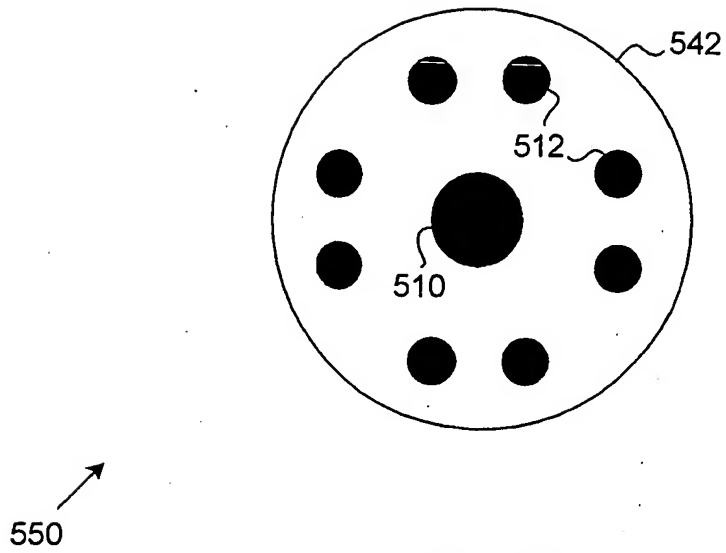


FIG. 5B

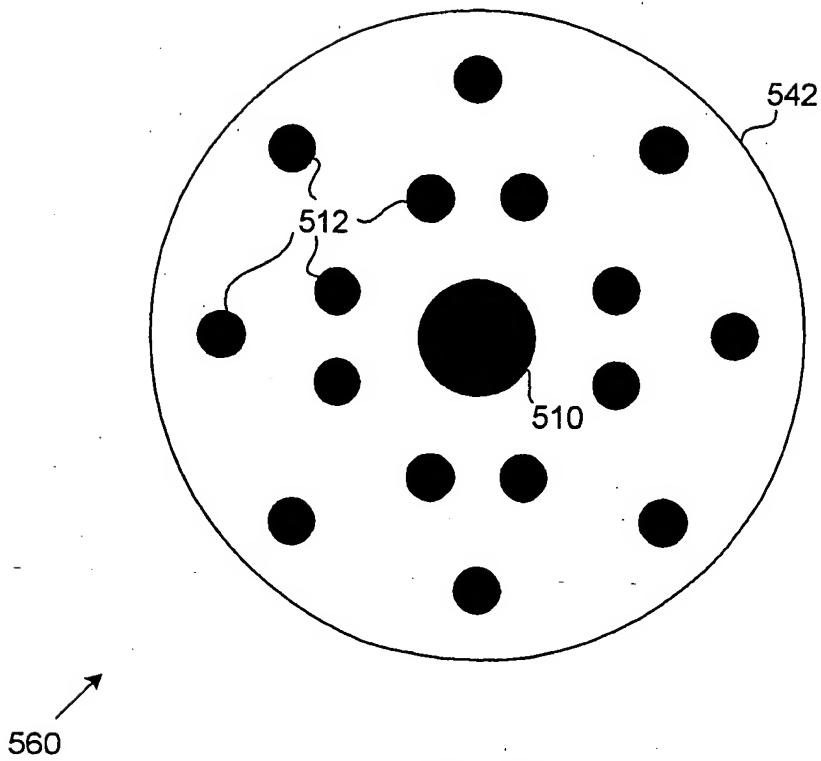


FIG. 5C

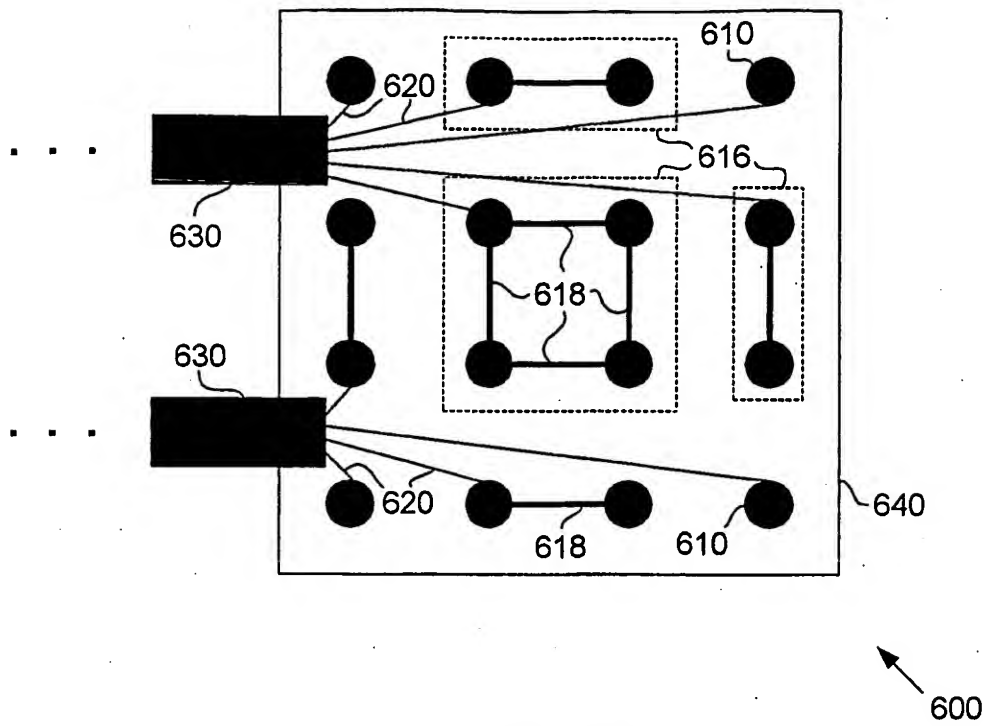


FIG. 6A

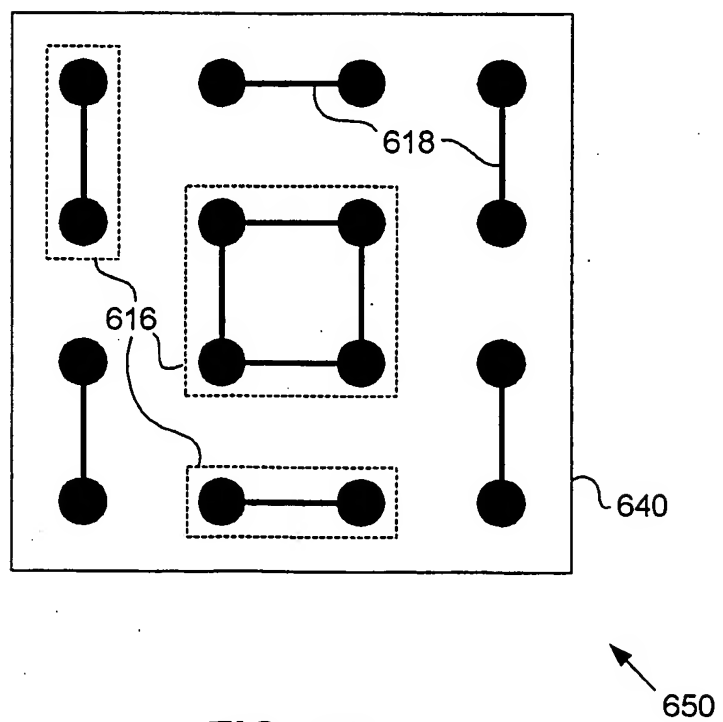


FIG. 6B

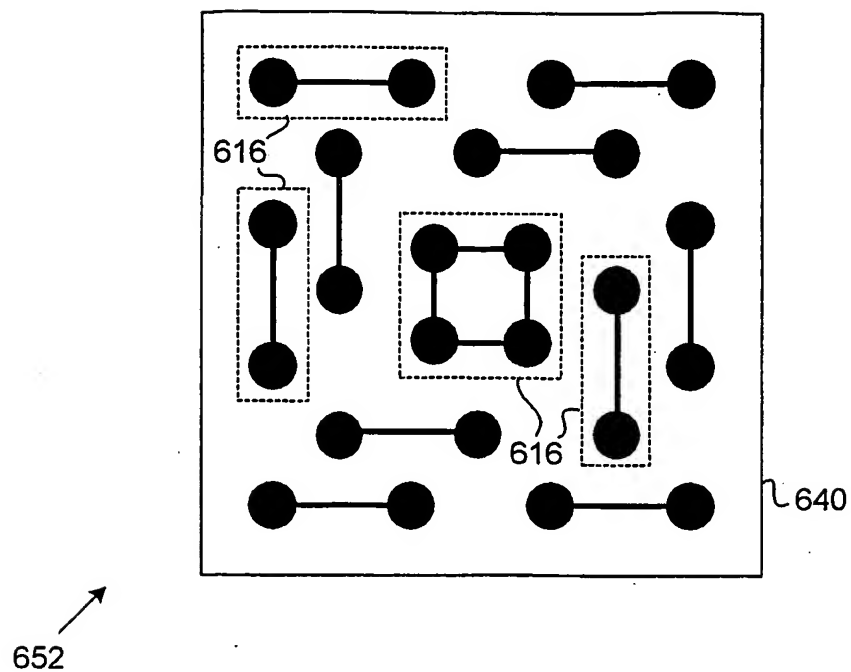


FIG. 6C

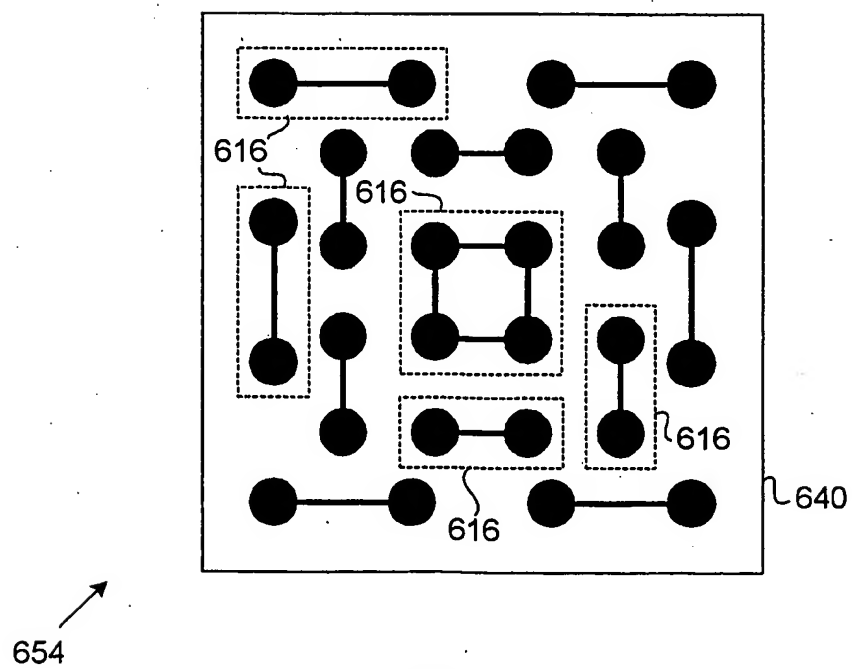


FIG. 6D

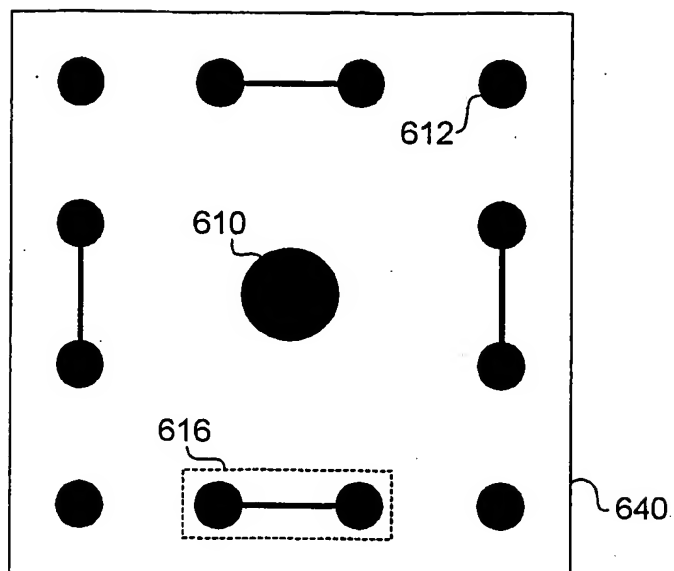


FIG. 6E

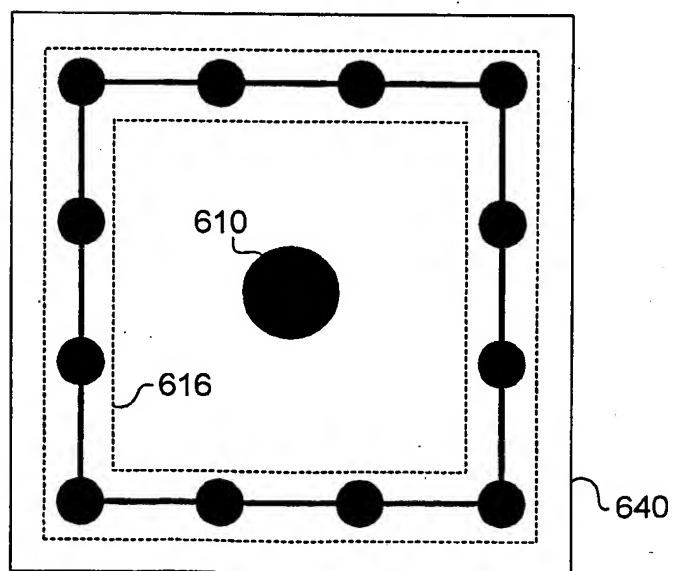


FIG. 6F

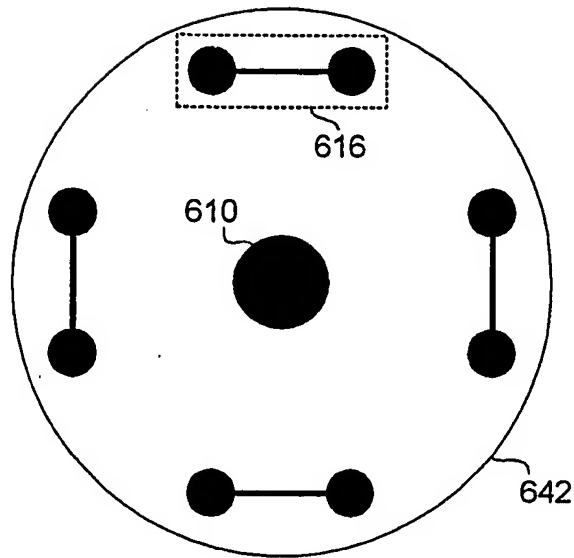


FIG. 6G

670

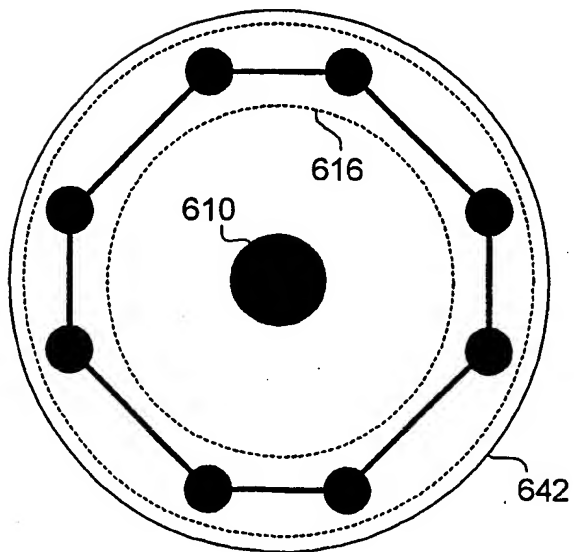


FIG. 6H

672

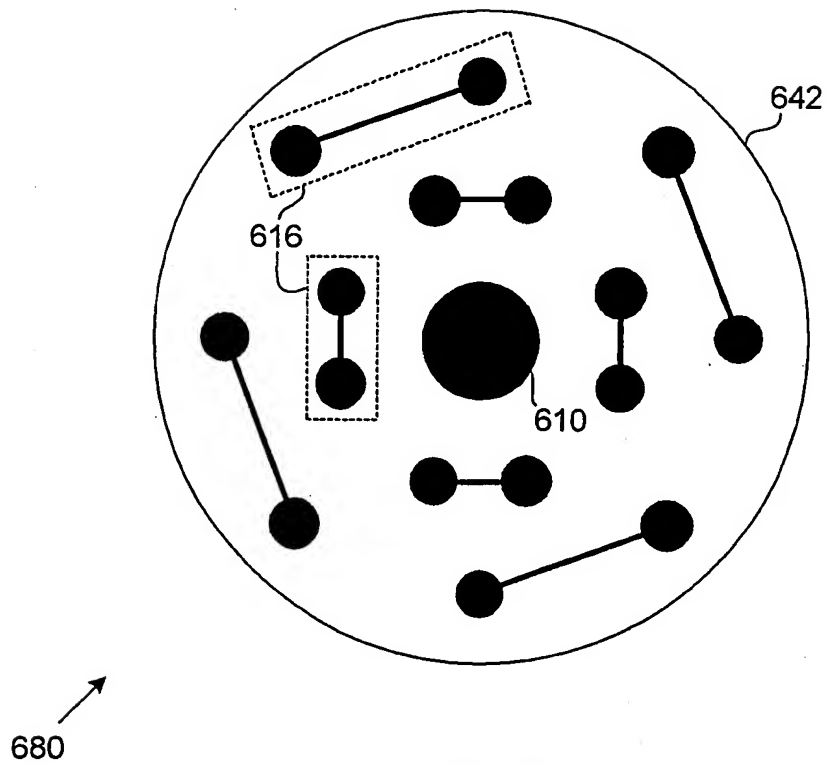


FIG. 6I



# PATENT COOPERATION TREATY

# PCT

## DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a), Rules 13ter.1(c) and Rule 39)

Applicant's or agent's file reference <b>337348025WO</b>	IMPORTANT DECLARATION	Date of mailing(day/month/year) <b>03/09/2003</b>
International application No. <b>PCT/US 03/ 09211</b>	International filing date(day/month/year) <b>26/03/2003</b>	(Earliest) Priority date(day/month/year) <b>28/03/2002</b>
International Patent Classification (IPC) or both national classification and IPC <b>A61N1/05</b>		
Applicant <b>VERTIS NEUROSCIENCE, INC.</b>		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established on the international application for the reasons indicated below**

1. ☒ The subject matter of the international application relates to:
  - a. ☐ scientific theories.
  - b. ☐ mathematical theories
  - c. ☐ plant varieties.
  - d. ☐ animal varieties.
  - e. ☐ essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes.
  - f. ☐ schemes, rules or methods of doing business.
  - g. ☐ schemes, rules or methods of performing purely mental acts.
  - h. ☐ schemes, rules or methods of playing games.
  - i. ☐ methods for treatment of the human body by surgery or therapy.
  - j. ☐ methods for treatment of the animal body by surgery or therapy.
  - k. ☐ diagnostic methods practised on the human or animal body.
  - l. ☐ mere presentations of information.
  - m. ☐ computer programs for which this International Searching Authority is not equipped to search prior art.
  
2. ☒ The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:
 

☐ the description
☒ the claims
☐ the drawings
  
3. ☐ The failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions prevents a meaningful search from being carried out:
 

☐ the written form has not been furnished or does not comply with the standard.
 ☐ the computer readable form has not been furnished or does not comply with the standard.
  
4. Further comments: SEE ADDITIONAL SHEET

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  <b>Eva San Miguel</b>
--	---

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 203

In view of the large number and also the wording of the independent claims presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present application fails to comply with the clarity and/or conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search is impossible. Consequently, no search report can be established for the present application.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**